APR - 4 2002

K020469

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories, Inc.
PO Box 45625
Omaha, NE 68145

Date Prepared: March 21, 2002

Names of Device:

Trade Name:	Cal-Chex CD Plus
Common Name:	Assayed hematology calibrator
Classification Names:	Calibrator for hemoglobin or hematocrit measurement (§864.8165) Calibrator for platelet counting (§864.8175) Hematology quality control mixture (§864.8625)
Classification Numbers:	81KRZ, 81KRY and 81GLQ

Predicate Devices: Cal-Chex manufactured by Streck Laboratories, Inc.

Description: Cal-Chex CD Plus is a suspension of stabilized human red blood cells, human white blood cells, and human platelets packaged in glass vials containing 3.0 mL volumes. Closures are injection molded polypropylene screw-top caps. The vials are packaged in a PVC clamshell.

Intended Use: Cal-Chex CD Plus is intended to be used as a calibrator for the calibration of WBC, RBC, Hgb, MCV, PLT and MPV (MPV on CD4000 only) on the Abbott Cell-Dyn 3200 and 4000 hematology instruments.

Comparison with Predicate Devices: Like Cal-Chex, Cal-Chex CD Plus is a product utilized to calibrate hematology instrumentation for specified parameters.

Unlike Cal-Chex, Cal-Chex CD Plus utilizes a formulation that has been optimized for use as a calibrator on Abbott Cel-Dyn® Systems employing Multiple Angle Polarized Scatter Separation (MAPSS™) technology.

Discussion of Tests: Three studies of Cal-Chex CD Plus were conducted:

I. Run-to-Run Reproducibility and Comparison to Whole Blood
II. Long Term and Open Vial Stabilities;
III. Verification as a calibrator. Study results showed Cal-Chex CD Plus to be consistently reproducible, substantially equivalent to whole blood calibration methods and stable for the entire product dating.

Conclusions Drawn From Tests: Study results show Cal-Chex CD Plus to be consistently reproducible and stable for the entire product dating. Cal-Chex CD Plus is a safe and effective alternative to Whole Blood Calibration when utilized as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Inc.
7002 South 109th Street
La Vista, Nebraska 68128

Re: k020469
Trade/Device Name: Cal-Chex CD Plus
Regulation Number: 21 CFR § 864.8150 Regulation Name: Calibrator for Cell Indices
Regulatory Class: II Product Code: KRX
Regulation Number: 21 CFR § 864.8165 Regulation Name: Calibrator for Hemoglobin or Hematocrit Measurement
Regulatory Class: II Product Code: KRZ
Regulation Number: 21 CFR § 864.8175 Regulation Name: Calibrator for Platelet Counting
Regulatory Class: II Product Code: KRY
Regulation Number: 21 CFR § 864.8185 Regulation Name: Calibrator for Red Cell and White Cell Counting
Regulatory Class: II Product Code: KSA
Dated: February 8, 2002
Received: February 12, 2002

Dear Mr. Kittelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K020469

Device Name: Cal-Chex CD Plus

Indications For Use: Cal-Chex CD Plus is used to calibrate the WBC, RBC, Hgb, MCV, PLT and MPV (MPV on CD4000 only) parameters on the Abbott Cell-Dyn 3200 and 4000 hematology instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Date: _____

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020469